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## EXHIBIT 8A

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Document Chronology/Due Diligence Logs for IND No. 47,838

# Regulatory Affairs

CARDS  
Chronology

JLP41868 30-Nov-2001 Application: IND 47838; GI198745 (5-alpha reductase inhibitor) 1 12:16:18

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
22-Aug-1994	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Export: Authorization	Export	Authorization	
26-Jan-1995	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Export: Authorization	Export	Authorization	
03-Feb-1995	GlaxoSmithKline FAX/E-mail IND 47,838; GI198745 (5-alpha reductase inhibitor) Export	Export		
23-Feb-1995	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Export: Authorization	Export	Authorization	
28-Feb-1995	GlaxoSmithKline Correspondence Pre-IND GI198745 (5-alpha reductase inhibitor) General Correspondence: Request for Comment	General Correspondence		

## Regulatory Affairs

### CARDS Chronology

JLP41868  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)  
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Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
24-Apr-1995	GlaxoSmithKline Correspondence	Initial Investigational New Drug Application	CMC Protocol(s) Included Study Reports	0000
		Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Initial Investigational New Drug Application: CMC, Protocol(s) Included, Study Reports Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0000			
28-Apr-1995	Food and Drug Administration Correspondence	Acknowledgement	IND # Assigned	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Acknowledgement: IND # Assigned			
09-May-1995	GlaxoSmithKline Correspondence	General Correspondence	Clinical Nonclinical	0001
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 001			

# Regulatory Affairs

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

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Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
23-May-1995	All			
	GlaxoSmithKline Correspondence	General Correspondence	Report of Selected Adverse Events	0002
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence: Report of Selected Adverse Events			
	Serial No.: 0002			
26-May-1995	GlaxoSmithKline Telephone Conversation	General Teleconference		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Record of Telecon			
26-May-1995	Food and Drug Administration Telephone Conversation	Comment/Information Request		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	FDA Comment			
05-Jun-1995	GlaxoSmithKline Correspondence	General Correspondence	Report of Selected Adverse Events	0003
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence: Report of Selected Adverse Events			
	Serial No.: 0003			
13-Jun-1995	GlaxoSmithKline Correspondence	General Correspondence	Clinical	0004
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence			
	Serial No.: 004			

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JLP41868  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
13-Sep-1995	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0005	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add Investigator Add	0005
26-Sep-1995	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0006	Information Amendment: Chemistry Manufacturing and Controls	CMC	0006
10-Oct-1995	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 007	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Other 1572 Change	0007
13-Oct-1995	GlaxoSmithKline Telephone Conversation  IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Telecon	General Teleconference	Nonclinical	

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JLP41868  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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16-Oct-1995	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Clinical	General Teleconference	Clinical	
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18-Oct-1995	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: CMC	Comment/Information Request	CMC	
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18-Oct-1995	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Minutes of Meeting: FDA Conference	Minutes of Meeting	FDA Conference	
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25-Oct-1995	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 008	General Correspondence		0008
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03-Nov-1995	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0009	General Correspondence	Clinical	0009
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## Regulatory Affairs

### CARDS Chronology

JLP41868 30-Nov-2001 Application: IND 47838; GI198745 (5-alpha reductase inhibitor) 12:16:18 6

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
08-Nov-1995		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 010	Protocol Amendment: New Investigator	Investigator Add	0010
13-Nov-1995		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0011	General Correspondence	CMC	0011
13-Dec-1995		GlaxoSmithKline Trip Report  IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Visit to FDA	Trip Report		
29-Jan-1996		GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls Information Amendment: Clinical Information Amendment: Nonclinical Protocol Amendment: New Protocol Protocol Amendment: New Investigator Protocol Amendment: Change in Protocol	CMC  Nonclinical  Investigator Add Clinical	0012

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JLP41868  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Chemistry Manufacturing and Controls  
Information Amendment: Clinical  
Information Amendment: Nonclinical  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Protocol Amendment: Change in Protocol  
Serial No.: 0012

29-Jan-1996		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0013	General Correspondence	Clinical	0013
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08-Feb-1996		Food and Drug Administration Telephone Conversation  IND 47,838; GI198745 (5-alpha reductase inhibitor) FDA Comment	Comment/Information Request	Clinical Nonclinical	
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09-Feb-1996		GlaxoSmithKline Telephone Conversation  IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Clinical	General Teleconference	Clinical	
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## Regulatory Affairs

### CARDS Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)  
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Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
12-Feb-1996		Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical Efficacy	
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical			
22-Feb-1996		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 014	Protocol Amendment: New Investigator	Investigator Add	0014
22-Feb-1996		GlaxoSmithKline Telephone Conversation  IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Electronic Submission	General Teleconference	Other	
29-Feb-1996		GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Nonclinical Serial No.: 015	Information Amendment: Nonclinical	Nonclinical Study Reports	0015
18-Mar-1996		GlaxoSmithKline Correspondence	General Correspondence	Clinical	0016

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence: Clinical  
Serial No.: 0016

22-Mar-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0017
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0017

02-Apr-1996	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Nonclinical	Comment/Information Request	Nonclinical	
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15-Apr-1996	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Clinical Nonclinical	
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19-Apr-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Nonclinical Serial No.: 0018	General Correspondence	Nonclinical	0018
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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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23-Apr-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0019
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0019

24-Apr-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0020
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Serial No.: 020

24-Apr-1996	Food and Drug Administration Correspondence	Comment/Information Request	Clinical	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Clinical

19-Jun-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 021	Protocol Amendment: New Investigator	Other 1572 Change	0021
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Date Range: All  
Date Communication Type Document Type Document Subtype Serial / Supp #

24-Jun-1996 GlaxoSmithKline Correspondence Annual Report CMC 0022

**Foreign Marketing Developments**

IND 47,838; GI198745 5-Alpha Reductase Inhibitor  
Annual Report  
Serial No.: 022

29-Jul-1996 GlaxoSmithKline Correspondence Response to FDA Request/Comment Nonclinical 0023

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Response to FDA Request/Comment: Nonclinical  
Serial No.: 0023

14-Aug-1996 GlaxoSmithKline Correspondence Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Protocol Amendment: Change in Protocol  
Investigator Add  
Clinical 0024

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Protocol Amendment: Change in Protocol  
Serial No.: 0024

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## Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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29-Aug-1996	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0025
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0025

11-Sep-1996	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol	Clinical	0026
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Serial No.: 026

02-Oct-1996	GlaxoSmithKline Correspondence	General Correspondence		0027
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence  
Serial No.: 027

02-Oct-1996	GlaxoSmithKline Correspondence	General Correspondence	Other	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence

09-Oct-1996	Food and Drug Administration Telephone Conversation	Comment/Information Request		
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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
All	"IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Request			

15-Oct-1996	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add	0028
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 028			

15-Oct-1996	GlaxoSmithKline Telephone Conversation	General Teleconference	Meeting Request	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Meeting Request			

23-Oct-1996	GlaxoSmithKline Correspondence	General Correspondence	Meeting Agenda or Details	0029
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Serial No.: 0029			

31-Oct-1996	Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details			

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30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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04-Nov-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0030	General Correspondence	CMC	0030
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06-Nov-1996	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical	Comment/Information Request	Clinical	
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15-Nov-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0031	General Correspondence	Clinical	0031
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18-Nov-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical, Meeting Agenda or Details Serial No.: 0032	General Correspondence	Clinical Meeting Agenda or Details	0032
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26-Nov-1996	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical Electronic Format	
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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Clinical, Electronic Format

18-Dec-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Agenda or Details Serial No.: 0033	General Correspondence	Meeting Agenda or Details	0033
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18-Dec-1996	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0034	General Correspondence	Clinical	0034
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28-Jan-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 035	Protocol Amendment: New Investigator	Other 1572 Change	0035
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30-Jan-1997	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Record of Telecon	General Teleconference	CMC	
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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
10-Feb-1997		GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0036
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Serial No.: 0036			
04-Mar-1997		GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Other 1572 Change	0037
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0037			
05-Mar-1997		GlaxoSmithKline Correspondence	General Correspondence		0038
		IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 038			
20-Mar-1997		GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add	0039
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 039			

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JLP41868					
17					
30-Nov-2001					
<b>Application:</b>	IND	47838; GI198745 (5-alpha reductase inhibitor)			
<b>Date Range:</b>	All				
<b>Date</b>	<b>Communication Type</b>	<b>Document Type</b>	<b>Document Subtype</b>	<b>Serial / Supp #</b>	
23-May-1997	GlaxoSmithKline Correspondence	General Correspondence		0040	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 040				
02-Jun-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator Information Amendment: Chemistry Manufacturing and Controls Protocol Amendment: Change in Protocol	Investigator Add CMC Clinical	0041	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Information Amendment: Chemistry Manufacturing and Controls Serial No.: 0041				
03-Jun-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0042	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0042				

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30-Nov-2001

**Application:** IND 47838; GI198745 (5-alpha reductase inhibitor)

<b>Date Range:</b>	<b>Date</b>	<b>All</b>	<b>Communication Type</b>	<b>Document Type</b>	<b>Document Subtype</b>	<b>Serial / Supp #</b>
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04-Jun-1997			" GlaxoSmithKline Correspondence	General Correspondence		0043
			IND 47,838; GI198745 (5-alpha reductase inhibitor)			
			General Correspondence			
			Serial No.: 043			

09-Jun-1997			GlaxoSmithKline Telephone Conversation	General Teleconference		
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			IND 47,838; GI198745 (5-alpha reductase inhibitor)			
			Record of Telecon			

11-Jun-1997			GlaxoSmithKline Correspondence	Annual Report		0044
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			IND 47,838; GI198745 (5-alpha reductase inhibitor)			
			Annual Report			
			Serial No.: 044			

02-Jul-1997			GlaxoSmithKline Correspondence	Information Amendment: Clinical		
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			IND 47,838; GI198745 (5-alpha reductase inhibitor)			
			Information Amendment: Clinical			
			Serial No.:045			

CMC  
Foreign Marketing Developments

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**Regulatory Affairs  
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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

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Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
22-Jul-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 046	Protocol Amendment: New Investigator	Investigator Add	0046
29-Jul-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 047	General Correspondence	CMC	0047
01-Aug-1997	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence	General Correspondence	Other	
07-Aug-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 048	Protocol Amendment: New Investigator	Other 1572 Change	0048
13-Aug-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator Amendment: Other	Investigator Add Transfer of Obligations to Contract	0049

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: New Investigator Amendment: Other, Transfer of Obligations to Contract Research Organization Serial No.: 0049			Research Organization	
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15-Aug-1997	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls		0050
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Chemistry Manufacturing and Controls  
Serial No.: 050

19-Aug-1997	Food and Drug Administration Correspondence	Comment/Information Request	CMC	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: CMC

20-Aug-1997	GlaxoSmithKline Correspondence	Minutes of Meeting	End of Phase II Meeting	0051
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Minutes of Meeting  
Serial No.: 051

28-Aug-1997	Food and Drug Administration Correspondence	Comment/Information Request		
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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28-Aug-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 052	Protocol Amendment: New Investigator	Investigator Add	0052
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08-Sep-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 053	General Correspondence	Clinical	0053
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10-Sep-1997	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Minutes of Meeting: End of Phase II Meeting	Minutes of Meeting	End of Phase II Meeting	
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11-Sep-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Protocol Amendment: New Protocol Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Other 1572 Change	0054
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22  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)  
Chronology  
12:16:18

Date Range: All  
Date Communication Type Document Type Document Subtype Serial / Supp #  
Serial No.: 0054

11-Sep-1997 GlaxoSmithKline Telephone Conversation General Teleconference

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference

19-Sep-1997 GlaxoSmithKline Telephone Conversation General Teleconference

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference

22-Sep-1997 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change  
0055

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0055

25-Sep-1997 GlaxoSmithKline Correspondence Protocol Amendment: Change in Protocol

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Serial No.: 56

Clinical  
0056

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**Application:** IND 47838; GI198745 (5-alpha reductase inhibitor)

<b>Date Range:</b>	<b>Date</b>	<b>Communication Type</b>	<b>Document Type</b>	<b>Document Subtype</b>	<b>Serial / Supp #</b>
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01-Oct-1997  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Draft Protocol

02-Oct-1997	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0057
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0057

09-Oct-1997	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls Information Amendment: Nonclinical	CMC Study Reports	0058
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 058  
Information Amendment: Chemistry Manufacturing and Controls, CMC  
Information Amendment: Nonclinical, Study Reports

10-Oct-1997	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add Other 1572 Change	0059
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0059



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Regulatory Affairs  
CARDS

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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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Date	All			
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16-Oct-1997	GlaxoSmithKline Correspondence	Annual Report	Changes to Investigator's Brochure Clinical Study Information Clinical	0060
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 060  
Annual Report: Changes to Investigator's Brochure  
Protocol Amendment: Change in Protocol

Protocol Amendment: Change in Protocol

21-Oct-1997	GlaxoSmithKline Correspondence	General Correspondence	Statistical	0061
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence  
Serial No.: 061

24-Oct-1997	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Clinical

27-Oct-1997	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls		0062
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Chemistry Manufacturing and Controls  
Serial No.: 062

JLP41868

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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

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Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
03-Nov-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0063	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0063
11-Nov-1997	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 064	Protocol Amendment: Change in Protocol	Clinical	0064
01-Dec-1997	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference	General Teleconference	Meeting Request	0065

JLP41868

Regulatory Affairs  
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## Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
02-Dec-1997		GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Statistical	
		IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Statistical			
03-Dec-1997		Food and Drug Administration Correspondence	Comment/Information Request	CMC	
		IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Other			
05-Dec-1997		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comments Serial No.: 067	Response to FDA Request/Comment	CMC	0067
05-Dec-1997		GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0066	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0066
08-Dec-1997		GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor)	Response to FDA Request/Comment	Clinical CMC	0068

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27  
30-Nov-2001  
Application: IND  
47838; GI198745 (5-alpha reductase inhibitor)  
Chronology  
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Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
		"General Correspondence Serial No.: 068			

15-Dec-1997	GlaxoSmithKline FAX/E-mail	Response to FDA Request/Comment General Memorandum	Statistical Meeting Agenda or Details	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Response to FDA Request/Comment: Statistical

15-Dec-1997	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: Other	General Teleconference	Other	
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08-Jan-1998	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0069	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0069
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22-Jan-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 070	Protocol Amendment: Change in Protocol	Clinical	0070
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# Regulatory Affairs CARDS

## Chronology

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JLP41868					
28					
30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)			
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
29-Jan-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0071	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0071				
04-Feb-1998	GlaxoSmithKline Correspondence	General Correspondence	Statistical	0072	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Statistical Serial No.: 072				
11-Feb-1998	GlaxoSmithKline Correspondence	General Correspondence	Clinical Draft Protocol	0073	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 073				
18-Feb-1998	GlaxoSmithKline Correspondence	Information Amendment: Clinical	Other	0075	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical Request for waivers for non-US Studies Serial No.: 075				

# Regulatory Affairs CARDS

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JLP41868  
29  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All  
Date Communication Type Document Type Document Subtype Serial / Supp #

18-Feb-1998 GlaxoSmithKline Correspondence General Correspondence Statistical 0074  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence  
Serial No.: 074

26-Feb-1998 GlaxoSmithKline Correspondence Protocol Amendment: Change in Protocol Clinical  
Protocol Amendment: New Investigator Investigator Add  
Other 1572 Change 0076

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0076

06-Mar-1998 GlaxoSmithKline Correspondence Information Amendment: Chemistry Manufacturing and Controls CMC 0077  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Chemistry Manufacturing and Controls, CMC  
Serial No.: 077

27-Mar-1998 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add  
Other 1572 Change 0078  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0078

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JLP41868  
30  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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02-Apr-1998	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical	Comment/Information Request	Clinical	
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03-Apr-1998	Food and Drug Administration Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request	Comment/Information Request	Statistical	
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09-Apr-1998	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: CMC	General Teleconference	CMC	
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17-Apr-1998	Food and Drug Administration Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Comment/Information Request: Clinical	Comment/Information Request	Clinical	
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23-Apr-1998	GlaxoSmithKline Telephone Conversation IND 47,838; GI198745 (5-alpha reductase inhibitor)	General Teleconference	CMC	
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30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)  
Chronology  
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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
27-Apr-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0079
28-Apr-1998	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0079	Protocol Amendment: Change in Protocol	Clinical	0080
30-Apr-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 081	Protocol Amendment: Change in Protocol	Clinical	0081
11-May-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 082	General Correspondence	Clinical	0082



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**Regulatory Affairs  
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30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)  
Chronology  
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Date Range:	All	Document Type	Document Subtype	Serial / Supp #
Date	Communication Type			
12-May-1998	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical Protocol	

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Clinical, Protocol

28-May-1998	Food and Drug Administration Correspondence	Comment/Information Request	Clinical Statistical	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Clinical, Statistical

29-May-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0083
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0083

29-May-1998	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Clinical Protocol	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Response to FDA Request/Comment: Clinical

# Regulatory Affairs CARDS

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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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09-Jun-1998	GlaxoSmithKline Correspondence	Annual Report	Adverse Event Summary Clinical Study Information CMC Outstanding Regulatory Business	0084
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Annual Report  
Serial No.: 084

19-Jun-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 085	General Correspondence	Clinical	0085
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22-Jun-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Protocol Serial No.: 086	Protocol Amendment: New Protocol		0086
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23-Jun-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0087
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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
Date		"Protocol Amendment: New Investigator Serial No.: 0087			

01-Jul-1998	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls	CMC	0088
	IND 47,838; GI198745 (5-alpha reductase inhibitor)	Information Amendment: Chemistry Manufacturing and Controls		
	Serial No.: 088			

09-Jul-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol	Clinical	0089
		Protocol Amendment: Change in Protocol		
		Protocol Amendment: New Investigator	Investigator Add	

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Protocol Amendment: Change in Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0089

31-Jul-1998	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol	Clinical	0090
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Protocol Amendment: Change in Protocol			
	Serial No.: 0090			

03-Aug-1998	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0091
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47838; GI198745 (5-alpha reductase inhibitor)

Communication Type  
Document Type  
Document Subtype  
Serial / Supp #

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0091

10-Aug-1998  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Serial No.: 092  
Protocol Amendment: Change in Protocol  
Clinical  
0092

31-Aug-1998  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0093  
Protocol Amendment: New Investigator  
Investigator Add  
Other 1572 Change  
0093

14-Sep-1998  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0094  
Protocol Amendment: New Investigator  
Investigator Add  
Other 1572 Change  
0094

06-Oct-1998  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0094  
Protocol Amendment: New Investigator  
Investigator Add  
Other 1572 Change  
0095

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Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date Communication Type

Document Type

Document Subtype  
Investigator Add

Serial / Supp #

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0095

13-Oct-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0096

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0096

28-Oct-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0097

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0097

06-Nov-1998 GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0098

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0098

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## Chronology

JLP41868  
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30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
All				
10-Nov-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 099	Protocol Amendment: Change in Protocol	Clinical	0099
18-Nov-1998	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0100	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0100
17-Dec-1998	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0101	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0101
22-Dec-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0102	Protocol Amendment: New Investigator	Other 1572 Change	0102
23-Dec-1998	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor)	Protocol Amendment: New Investigator	Investigator Add	0103

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JLP4186838									
30-Nov-2001									
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology						
Date Range:	All								
Date	Communication Type	Document Type				Document Subtype		Serial / Supp #	
	Protocol Amendment: New Investigator								
	Serial No.: 103								
13-Jan-1999	GlaxoSmithKline Correspondence	Information Amendment: Chemistry Manufacturing and Controls				CMC		0104	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)								
	Information Amendment: Chemistry Manufacturing and Controls, CMC								
	Serial No.: 104								
15-Jan-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator				Investigator Add		0105	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					Other 1572 Change			
	Protocol Amendment: New Investigator								
	Serial No.: 0105								
02-Feb-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator				Investigator Add		0106	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					Other 1572 Change			
	Protocol Amendment: New Investigator								
	Serial No.: 0106								
18-Feb-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol						0107	
		Protocol Amendment: New Investigator							
	IND 47,838; GI198745 (5-alpha reductase inhibitor)					Investigator Add			
	Protocol Amendment: New Investigator								
	Serial No.: 0106								

JLP41868

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Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range:

All

Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0107

03-Mar-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0108

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Investigator

Serial No.: 0108

04-Mar-1999

GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing  
and Controls

CMC

0109

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Information Amendment: Chemistry Manufacturing and Controls, CMC

Serial No.: 109

08-Mar-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator

Investigator Add

0110

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Protocol

Protocol Amendment: New Investigator

Serial No.: 110

12-Mar-1999

GlaxoSmithKline Correspondence

Protocol Amendment: Change in Protocol

Clinical

0111

IND 47,838; GI198745 (5-alpha reductase inhibitor)



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Chronology

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JLP41868					
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30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)			
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
	"Protocol Amendment: Change in Protocol Serial No.: 111				
19-Mar-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0112	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0112				
02-Apr-1999	GlaxoSmithKline Correspondence	Amendment: Other	Change in Medical Monitor	0113	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Amendment: Other, Change in Medical Monitor Serial No.: 113				
06-Apr-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0114	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 114				
27-Apr-1999	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0115	
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0115				

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JLP41868 41 30-Nov-2001 Application: IND 47838; GI198745 (5-alpha reductase inhibitor) Chronology 12:16:18

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
29-Apr-1999		GlaxoSmithKline Telephone Conversation	General Teleconference	CMC	
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		General Teleconference: CMC			
19-May-1999		GlaxoSmithKline Correspondence	General Correspondence	Statistical	0116
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		General Correspondence: Statistical			
		Serial No.: 0116			
21-May-1999		GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0117
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		Protocol Amendment: New Investigator			
		Serial No.: 0117			
09-Jun-1999		GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol	Clinical	0119
			Protocol Amendment: Change in Protocol	Investigator Add	
			Protocol Amendment: New Investigator		
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		Protocol Amendment: New Protocol			
		Protocol Amendment: Change in Protocol			
		Protocol Amendment: New Investigator			
		Serial No.: 0119			

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Chronology

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Application:

IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

09-Jun-1999

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0118  
0018

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0118

10-Jun-1999

Food and Drug Administration Telephone  
Conversation  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Status Update

General Teleconference

Status Update

22-Jun-1999

GlaxoSmithKline Correspondence

Annual Report

Adverse Event Summary  
Clinical Study Information  
CMC  
Investigational Plan  
Outstanding Regulatory Business

0120

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Annual Report  
Serial No.: 0120

24-Jun-1999

GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor) Injection, 0.0111 mg GI198745X per mL  
General Correspondence: CMC -Phase I IV Solution

General Correspondence

CMC

0121

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**Regulatory Affairs  
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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Document Type	Document Subtype	Serial / Supp #
Date	Communication Type			
	Serial No.: 0121			

24-Jun-1999 GlaxoSmithKline Correspondence General Correspondence CMC 0122

IND 47,838; GI198745 Soft Gelatin Capsules, 0.5 mg  
General Correspondence: CMC - Specification and Test Methods  
Serial No.: 0122

02-Jul-1999 GlaxoSmithKline Correspondence Protocol Amendment: New Protocol Protocol Amendment: New Investigator Investigator Add 0123

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0123

06-Jul-1999 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Other 1572 Change 0124

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0124

15-Jul-1999 Food and Drug Administration Telephone Conversation Comment/Information Request Other

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Other

# Regulatory Affairs CARDS

Chronology

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JLP41868				
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30-Nov-2001				
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)		
Date Range:	All			
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
20-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0125	Protocol Amendment: New Investigator	Other 1572 Change	0125
21-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0126	Protocol Amendment: Change in Protocol	Clinical	0126
22-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence Serial No.: 0127	General Correspondence	Clinical	0127
30-Jul-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0128	Protocol Amendment: New Investigator	Other 1572 Change	0128
17-Aug-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0129	Protocol Amendment: New Investigator	Other 1572 Change	0129

JLP41868

**Regulatory Affairs  
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30-Nov-2001

Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range:  
Date

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

01-Sep-1999

GlaxoSmithKline Correspondence

Information Amendment: Chemistry Manufacturing  
and Controls

CMC

0130

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Chemistry Manufacturing and Controls, CMC  
Serial No.: 0130

01-Sep-1999

GlaxoSmithKline Telephone Conversation

General Teleconference

Clinical  
Safety

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Clinical, Safety

09-Sep-1999

GlaxoSmithKline Correspondence

General Correspondence

Meeting Agenda or Details

0131

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence: Meeting Agenda or Details  
Serial No.: 0131

IND 53,551; GI262570X

General Correspondence: Meeting Agenda or Details  
Serial No.: 0072

10-Sep-1999

Food and Drug Administration Telephone  
Conversation

General Teleconference

Status Update

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Status Update

# Regulatory Affairs CARDS

JLP41868

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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

12:16:18

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

24-Sep-1999

GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0132

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0132

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0021

10-Day ADR Report: Initial

26-Oct-1999

GlaxoSmithKline Correspondence

Improper Conduct by an Investigator

0133

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Improper Conduct by an Investigator

Serial No.: 0133

28-Oct-1999

GlaxoSmithKline Correspondence

General Correspondence

Statistical

0134

IND 47,838; GI198745 (5-alpha reductase inhibitor)

General Correspondence: Statistical

Serial No.: 0134

28-Oct-1999

GlaxoSmithKline Correspondence

Minutes of Meeting

FDA Conference

0135

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Minutes of Meeting

Serial No.: 0135

28-Oct-1999

GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0136

IND 47,838; GI198745 (5-alpha reductase inhibitor)

JLP41868

**Regulatory Affairs  
CARDS**

47  
30-Nov-2001  
Application: IND  
IND 47838; GI198745 (5-alpha reductase inhibitor)  
Chronology  
12:16:18

Date Range: All  
Date  
Communication Type  
Document Type  
Document Subtype  
Serial / Supp #

Serial No.: 0136  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0023  
10-Day ADR Report: Initial

01-Nov-1999  
GlaxoSmithKline Correspondence  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
0137

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Protocol Amendment: New Investigator  
Serial No.: 0137  
Investigator Add

02-Nov-1999  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Clinical, Statistical  
Serial No.: 0138  
Information Amendment: Clinical  
Statistical  
0138

10-Nov-1999  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence  
Serial No.: 0139  
General Correspondence  
Clinical  
0139

22-Nov-1999  
GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Serial No.: 0140  
Protocol Amendment: Change in Protocol  
Clinical  
0140



# Regulatory Affairs CARDS

Chronology

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48

30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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03-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0141	Protocol Amendment: Change in Protocol	Clinical	0141
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08-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0142	Protocol Amendment: New Investigator	Investigator Add	0142
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10-Dec-1999	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0143 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0024 10-Day ADR Report: Follow-up	15-Day ADR Report	Follow-up	0143
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15-Dec-1999	GlaxoSmithKline Correspondence  IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0144	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0144
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# Regulatory Affairs CARDS

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JLP41868  
49  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All Date Communication Type Document Type Document Subtype Serial / Supp #

22-Dec-1999 GlaxoSmithKline Correspondence General Correspondence Statistical 0145  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence: Statistical  
Serial No.: 0145

28-Dec-1999 Food and Drug Administration Telephone Comment/Information Request Statistical  
Conversation  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Statistical

05-Jan-2000 GlaxoSmithKline Correspondence 15-Day ADR Report Initial 0146  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0146  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0025  
10-Day ADR Report: Initial

05-Jan-2000 Food and Drug Administration Telephone General Teleconference Other  
Conversation  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Other

06-Jan-2000 Food and Drug Administration Telephone General Teleconference Other  
Conversation  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Other

JLP41868

Regulatory Affairs  
CARDS

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30-Nov-2001

Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All  
Date

Communication Type

Document Type

Document Subtype

Serial / Supp #

10-Jan-2000

Food and Drug Administration Telephone  
Conversation  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Comment/Information Request: Other

Comment/Information Request

Other

11-Jan-2000

GlaxoSmithKline Correspondence  
  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0147

Protocol Amendment: New Investigator

Other 1572 Change  
Investigator Add

0147

11-Jan-2000

GlaxoSmithKline Telephone Conversation  
  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Response to FDA Request/Comment: Safety

Response to FDA Request/Comment

Safety

17-Jan-2000

GlaxoSmithKline FAX/E-mail  
  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Response to FDA Request/Comment: Other

Response to FDA Request/Comment

Other

19-Jan-2000

GlaxoSmithKline Correspondence

15-Day ADR Report

Follow-up

0148

JLP41868

**Regulatory Affairs  
CARDS**

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30-Nov-2001

Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Communication Type

Document Type

Document Subtype

Serial / Supp #

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0148

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0027

10-Day ADR Report: Follow-up

02-Feb-2000

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0150

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Investigator

Serial No.: 0150

02-Feb-2000

GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0149

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Serial No.: 0149

IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia

Serial No.: 0028

10-Day ADR Report: Initial

24-Feb-2000

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0151

IND 47,838; GI198745 (5-alpha reductase inhibitor)

Protocol Amendment: New Investigator

Serial No.: 0151

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**Regulatory Affairs  
CARDS**

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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
14-Mar-2000		GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Amendment: Other, Letter of Authorization Serial No.: 0153	Amendment: Other	Letter of Authorization	0153

14-Mar-2000	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator	Clinical Investigator Add	0152
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Protocol Amendment: New Investigator Serial No.: 0152			

30-Mar-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0154
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0154 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0030 10-Day ADR Report: Follow-up			

14-Apr-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add	0155
	IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0155			

21-Apr-2000	Food and Drug Administration Telephone Conversation	General Teleconference	Other	
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**Regulatory Affairs  
CARDS**

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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Other

03-May-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0156
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0156  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0031  
10-Day ADR Report: Initial

05-May-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0157
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0157  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0032  
10-Day ADR Report: Follow-up

19-May-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0158
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0158

23-May-2000	GlaxoSmithKline FAX/E-mail	General Memorandum	Safety
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# Regulatory Affairs CARDS

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54					
30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology		
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
23-May-2000	GlaxoSmithKline Telephone Conversation	7-Day Safety Report	Safety		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	7-Day Safety Report				
24-May-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0159	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Serial No.: 0159				
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia				
	Serial No.: 0033				
	10-Day ADR Report: Initial				
09-Jun-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0160	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Serial No.: 0160				
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia				
	Serial No.: 0034				
	10-Day ADR Report: Follow-up				
15-Jun-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0161	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Protocol Amendment: New Investigator				
	Serial No.: 0161				

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55  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: All  
Date Communication Type Document Type Document Subtype Serial / Supp #

23-Jun-2000 GlaxoSmithKline Correspondence 15-Day ADR Report Follow-up 0162  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0162  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0035  
10-Day ADR Report: Follow-up

27-Jun-2000 GlaxoSmithKline Correspondence Annual Report Clinical Study Information Investigational Plan 0163

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Annual Report  
Serial No.: 0163

13-Jul-2000 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Investigator Add Other 1572 Change 0164

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0164

13-Jul-2000 GlaxoSmithKline Correspondence 15-Day ADR Report Follow-up 0165

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0165  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0036  
10-Day ADR Report: Follow-up



JLP41868

**Regulatory Affairs  
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Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

17-Jul-2000

GlaxoSmithKline Telephone Conversation

7-Day Safety Report

Safety

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
7-Day Safety Report

18-Jul-2000

GlaxoSmithKline Correspondence

15-Day ADR Report

Initial

0166

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0166  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0037  
10-Day ADR Report: Initial

08-Aug-2000

GlaxoSmithKline Correspondence

Protocol Amendment: Change in Protocol

Clinical

0167

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Serial No.: 0167

16-Aug-2000

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0168

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0168

57

30-Nov-2001

Application: IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

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Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
17-Aug-2000		GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0169
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		Serial No.: 0169			
		IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
		Serial No.: 0038			
		10-Day ADR Report: Follow-up			

21-Aug-2000	GlaxoSmithKline Telephone Conversation	7-Day Safety Report	Safety
	IND 47,838; GI198745 (5-alpha reductase inhibitor)		
	7-Day Safety Report		

22-Aug-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0170
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Serial No.: 0170			
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
	Serial No.: 0039			
	10-Day ADR Report: Initial			

24-Aug-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0171
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Serial No.: 0171			
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
	Serial No.: 0040			
	10-Day ADR Report: Initial			

# Regulatory Affairs CARDS

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Date Range: All Date Communication Type Document Type Document Subtype Serial / Supp #

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Information Amendment: Clinical, Other  
Serial No.: 0172

General Correspondence

Draft Protocol

0173

28-Aug-2000 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: CMC Serial No.: 0173

General Correspondence

CMC

0173

19-Sep-2000 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Clinical Serial No.: 0174

General Correspondence

Clinical

0174

20-Sep-2000 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0175

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0175

22-Sep-2000 GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Meeting Request Serial No.: 0176

General Correspondence

Meeting Request

0176

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30-Nov-2001

Chronology

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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
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26-Sep-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Protocol Protocol Amendment: New Investigator	Investigator Add	0177
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Protocol  
Serial No.: 0177

26-Sep-2000	Food and Drug Administration Telephone Conversation	General Teleconference	Status Update	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Status Update

27-Sep-2000	GlaxoSmithKline Correspondence	General Correspondence	CMC	0178
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence: CMC Meeting Request  
Serial No.: 0178

03-Oct-2000	Food and Drug Administration Telephone Conversation	General Teleconference	Meeting Request	
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: Meeting Request

06-Oct-2000	Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details	
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30-Nov-2001				
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology	
Date Range:	All			
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Correspondence: Meeting Agenda or Details			
13-Oct-2000	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC Meeting Agenda or Details	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	General Teleconference: CMC, Meeting Agenda or Details			
17-Oct-2000	Food and Drug Administration Correspondence	Comment/Information Request	Clinical Protocol	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Comment/Information Request			
17-Oct-2000	Food and Drug Administration Correspondence	Comment/Information Request	Clinical	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Comment/Information Request			
19-Oct-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0179

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Chronology

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Date Range:  
Date

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0179

23-Oct-2000

Food and Drug Administration FAX/E-mail

General Memorandum  
Comment/Information Request

Meeting Agenda or Details  
CMC

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Memorandum: Meeting Agenda or Details  
Comment/Information Request: CMC

27-Oct-2000

GlaxoSmithKline Correspondence

General Correspondence

Clinical  
Meeting Agenda or Details  
Nonclinical  
Protocol

0180

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Correspondence: Meeting Agenda or Details  
Pre-NDA Meeting Information Package  
Serial No.: 0180

30-Oct-2000

GlaxoSmithKline Correspondence  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Serial No.: 0181

Protocol Amendment: Change in Protocol

Clinical

0181

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**Regulatory Affairs  
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30-Nov-2001

**Chronology**

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**Application:** IND 47838; GI198745 (5-alpha reductase inhibitor)

<b>Date Range:</b> <b>Date</b>	<b>Communication Type</b>	<b>Document Type</b>	<b>Document Subtype</b>	<b>Serial / Supp #</b>
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02-Nov-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: Change in Protocol Serial No.: 0182	Protocol Amendment: Change in Protocol	Clinical	0182
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06-Nov-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0183 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0041 10-Day ADR Report: Initial	15-Day ADR Report	Initial	0183
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07-Nov-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical, Statistical Serial No.: 0184	Information Amendment: Clinical	Statistical	0184
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09-Nov-2000	GlaxoSmithKline Telephone Conversation  IND 47,838; GI198745 (5-alpha reductase inhibitor) General Teleconference: CMC	General Teleconference	CMC Meeting Agenda or Details	
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Regulatory Affairs  
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## Chronology

30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
09-Nov-2000	Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	General Correspondence: Meeting Agenda or Details				
17-Nov-2000	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change		0185
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Protocol Amendment: New Investigator				
	Serial No.: 0185				
17-Nov-2000	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	CMC		0186
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Response to FDA Request/Comment: CMC				
	Serial No.: 0186				
27-Nov-2000	Food and Drug Administration Telephone Conversation	Comment/Information Request	Clinical		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Comment/Information Request: Clinical				
	Comment on Pre-NDA Meeting Package				
30-Nov-2000	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up		0187
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Serial No.: 0187				
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia				



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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

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Regulatory Affairs  
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Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
Date					
	Serial No.: 0042				
	10-Day ADR Report: Follow-up				
01-Dec-2000	GlaxoSmithKline Correspondence	Protocol Amendment: Change in Protocol	Clinical	0188	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Protocol Amendment: Change in Protocol				
	Serial No.: 0188				
05-Dec-2000	GlaxoSmithKline Trip Report	Type	Pre-NDA Meeting		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	Type: Pre-NDA Meeting				
05-Dec-2000	Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details		
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	General Correspondence: Meeting Agenda or Details				
06-Dec-2000	GlaxoSmithKline Correspondence	General Correspondence	Meeting Agenda or Details	0189	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)				
	General Correspondence: Meeting Agenda or Details				
	Serial No.: 0189				
08-Dec-2000	GlaxoSmithKline Correspondence	General Correspondence	Nonclinical	0190	

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JLP41868					
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30-Nov-2001					
Application:	IND	47838; GI198745 (5-alpha reductase inhibitor)	Chronology		
Date Range:	All				
Date	Communication Type	Document Type	Document Subtype	Serial / Supp #	
	"IND 47,838; GI198745 (5-alpha reductase inhibitor) General Correspondence: Nonclinical Serial No.: 0190				
14-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0191	Protocol Amendment: New Investigator	Other 1572 Change	0191	
15-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Response to FDA Request/Comment: Clinical, Draft Protocol Serial No.: 0192	Response to FDA Request/Comment	Clinical Draft Protocol	0192	
18-Dec-2000	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0193 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia Serial No.: 0043 10-Day ADR Report: Follow-up	15-Day ADR Report	Follow-up	0193	
02-Jan-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Serial No.: 0194 IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia	15-Day ADR Report	Initial	0194	

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30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
	All				
	Serial No.: 0044				
	10-Day ADR Report: Initial				

Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
03-Jan-2001	Food and Drug Administration Correspondence	Comment/Information Request	Statistical	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Comment/Information Request: Statistical			

Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
08-Jan-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0195
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Serial No.: 0195			
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
	Serial No.: 0045			
	10-Day ADR Report: Follow-up			

Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
09-Jan-2001	GlaxoSmithKline Telephone Conversation	7-Day Safety Report	Safety	
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	7-Day Safety Report			

Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
10-Jan-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0196
	IND 47,838; GI198745 (5-alpha reductase inhibitor)			
	Serial No.: 0196			
	IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
	Serial No.: 0046			
	10-Day ADR Report: Initial			

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Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range:  
Date

All

Communication Type

Document Type

Document Subtype

Serial / Supp #

11-Jan-2001

GlaxoSmithKline Correspondence

Protocol Amendment: New Investigator

Investigator Add  
Other 1572 Change

0197

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0197

12-Jan-2001

GlaxoSmithKline Correspondence

15-Day ADR Report

Follow-up

0198

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0198  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0048  
10-Day ADR Report: Follow-up

02-Feb-2001

GlaxoSmithKline Correspondence

Response to FDA Request/Comment

CMC

0199

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Response to FDA Request/Comment: CMC Teleconference Held on November 9, 2000  
Serial No.: 0199

08-Feb-2001

GlaxoSmithKline Correspondence

Protocol Amendment: Change in Protocol  
Protocol Amendment: New Investigator

Clinical  
Investigator Add  
Other 1572 Change

0200

IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: Change in Protocol  
Protocol Amendment: New Investigator

# Regulatory Affairs CARDS

JLP41868 68 30-Nov-2001 Application: IND 47838; GI198745 (5-alpha reductase inhibitor) Chronology 12:16:18

Date Range: All Date Communication Type Document Type Document Subtype Serial / Supp #  
Serial No.: 0200

08-Feb-2001 GlaxoSmithKline Telephone Conversation General Teleconference CMC  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
General Teleconference: CMC

19-Feb-2001 GlaxoSmithKline Correspondence 15-Day ADR Report Initial 0201  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0201  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0049  
10-Day ADR Report: Initial

05-Mar-2001 GlaxoSmithKline Correspondence 15-Day ADR Report Follow-up 0202  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0202  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0050  
10-Day ADR Report: Follow-up

09-Mar-2001 GlaxoSmithKline Correspondence Protocol Amendment: New Investigator Other 1572 Change 0203  
IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0203

# Regulatory Affairs CARDS

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JLP41868  
69  
30-Nov-2001  
Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Chronology

Date Range: Date	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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30-Mar-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Information Amendment: Clinical Serial No.: 0204	Information Amendment: Clinical	Other	0204
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09-Apr-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0205	Protocol Amendment: New Investigator	Other 1572 Change	0205
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08-May-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0206	Protocol Amendment: New Investigator	Other 1572 Change	0206
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07-Jun-2001	GlaxoSmithKline Correspondence IND 47,838; GI198745 (5-alpha reductase inhibitor) Protocol Amendment: New Investigator Serial No.: 0207	Protocol Amendment: New Investigator	Other 1572 Change	0207
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21-Jun-2001	GlaxoSmithKline Correspondence	Annual Report	Adverse Event Summary Changes to Investigator's Brochure Clinical Study Information CMC	0208
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Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Annual Report  
Serial No.: 0208

18-Jul-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0209
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0209  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0051  
15-Day ADR Report: Initial

25-Jul-2001	GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Other 1572 Change	0210
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Protocol Amendment: New Investigator  
Serial No.: 0210

27-Jul-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0211
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0211  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0052  
15-Day ADR Report: Follow-up

06-Aug-2001	GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0212
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IND 47,838; GI198745 (5-alpha reductase inhibitor)  
Serial No.: 0212

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30-Nov-2001

Application: IND 47838; GI198745 (5-alpha reductase inhibitor)

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Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
	All				
		IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
		Serial No.: 0053			
		15-Day ADR Report: Follow-up			
31-Aug-2001		GlaxoSmithKline Correspondence	General Correspondence	Clinical	0213
		IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
		Serial No.: 0054			
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		Serial No.: 0213			
		General Correspondence: Clinical			
05-Sep-2001		GlaxoSmithKline Correspondence	15-Day ADR Report	Initial	0214
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		Serial No.: 0214			
		IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia			
		Serial No.: 0055			
		15-Day ADR Report: Initial			
06-Sep-2001		GlaxoSmithKline Correspondence	Protocol Amendment: New Investigator	Investigator Add Other 1572 Change	0215
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			
		Protocol Amendment: New Investigator			
		Serial No.: 0215			
20-Sep-2001		GlaxoSmithKline Correspondence	15-Day ADR Report	Follow-up	0216
		IND 47,838; GI198745 (5-alpha reductase inhibitor)			



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30-Nov-2001

Application:

IND

47838; GI198745 (5-alpha reductase inhibitor)

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Date Range:	Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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Serial No.: 0216  
IND 54,319; GI198745 (5-alpha reductase inhibitor) Alopecia  
Serial No.: 0056  
15-Day ADR Report: Follow-up

08-Oct-2001	GlaxoSmithKline Correspondence	IND 47,838; GI198745 (5-alpha reductase inhibitor)	Protocol Amendment: New Investigator	Other 1572 Change	0217
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Protocol Amendment: New Investigator  
Serial No.: 0217

07-Nov-2001	GlaxoSmithKline Correspondence	IND 47,838; GI198745 (5-alpha reductase inhibitor)	Protocol Amendment: New Investigator	Other 1572 Change	0218
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Protocol Amendment: New Investigator  
Serial No.: 0218

30-Nov-2001	GlaxoSmithKline Correspondence		General Correspondence		0219
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NAS; Not Product Specific  
General Correspondence: Other

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## EXHIBIT 8B

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Document Chronology/Due Diligence Logs for NDA 21-319

# Regulatory Affairs

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JLP41868  
30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
22-Sep-2000		Food and Drug Administration FAX/E-mail	General Memorandum	Status Update	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Memorandum: User Fee ID #			
06-Oct-2000		Food and Drug Administration Correspondence	General Correspondence	Meeting Agenda or Details	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: Meeting Agenda or Details			
19-Dec-2000		GlaxoSmithKline Correspondence	User Fee	Establishment With Clinical Data	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules User Fee ID Number 4030: Establishment With Clinical Data			
19-Dec-2000		Food and Drug Administration Telephone Conversation	General Teleconference	Status Update	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: Status Update			
19-Dec-2000		GlaxoSmithKline Telephone Conversation	General Teleconference	Request Status Update	
		NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: Request Status Update			

# Regulatory Affairs

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30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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21-Dec-2000	GlaxoSmithKline Correspondence	General Correspondence	CMC Field Copy	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy			

21-Dec-2000	GlaxoSmithKline Correspondence	Original Submission User Fee General Correspondence	Establishment Clinical CMC Field Copy DMF Nonclinical Patent Information	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Original Submission

02-Jan-2001	Food and Drug Administration Telephone Conversation NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Desk Copies	Comment/Information Request	Other	
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JLP41868  
30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
03-Jan-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Desk Copies	Response to FDA Request/Comment	Other	
26-Jan-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment	Response to FDA Request/Comment	Clinical Statistical	
01-Feb-2001	GlaxoSmithKline Telephone Conversation  NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC	Response to FDA Request/Comment	CMC	
01-Feb-2001	GlaxoSmithKline Telephone Conversation  NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC	Response to FDA Request/Comment	CMC	

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30-Nov-2001

Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All

Date Communication Type

Document Type

Document Subtype

Serial / Supp #

02-Feb-2001 "GlaxoSmithKline Telephone Conversation

Response to FDA Request/Comment

CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: CMC

06-Feb-2001 Food and Drug Administration Telephone  
Conversation

Comment/Information Request

Clinical  
Statistical

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Comment/Information Request

08-Feb-2001 Food and Drug Administration Telephone  
Conversation

Comment/Information Request

CMC  
Electronic Format  
Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Comment/Information Request

08-Feb-2001 GlaxoSmithKline Telephone Conversation

General Teleconference

Clinical  
CMC  
Meeting Agenda or Details

NDA 21-319; Dutasteride Soft-Gelatin Capsules

# Regulatory Affairs

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JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All Date Communication Type Document Type Document Subtype Serial / Supp #

"General Teleconference: Meeting Agenda or Details

13-Feb-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Clinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request for Information on Clinical Investigators

21-Feb-2001 GlaxoSmithKline Correspondence General Correspondence Meeting Agenda or Details  
Other

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: Meeting Agenda or Details, Other

01-Mar-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment Clinical  
CMC  
Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment

20-Apr-2001 GlaxoSmithKline Correspondence 120-Day Safety Update Safety

NDA 21-319; Dutasteride Soft-Gelatin Capsules

# Regulatory Affairs

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JLP41868  
30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
"120-Day Safety Update: Safety				
07-May-2001	GlaxoSmithKline FAX/E-mail  NDA 21-319; Dutasteride Soft-Gelatin Capsules General Memorandum: CMC	General Memorandum	CMC	
08-May-2001	GlaxoSmithKline Telephone Conversation  NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Nonclinical	
08-May-2001	Food and Drug Administration Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting	Minutes of Meeting	FDA Conference	
09-May-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC	General Correspondence	CMC	
15-May-2001	GlaxoSmithKline Correspondence	General Correspondence	CMC	



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30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: CMC

12-Jun-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Teleconference: CMC

12-Jun-2001	Food and Drug Administration Correspondence	Minutes of Meeting Comment/Information Request	FDA Conference CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Minutes of Meeting: FDA Conference

14-Jun-2001	GlaxoSmithKline Telephone Conversation	General Teleconference	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Teleconference: CMC

15-Jun-2001	GlaxoSmithKline Correspondence	Amendment to Pending Application	Clinical Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules

# Regulatory Affairs

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JLP41868 30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All Communication Type Document Type Document Subtype Serial / Supp #

"Amendment to Pending Application: Clinical, Nonclinical

27-Jun-2001 GlaxoSmithKline Correspondence Response to FDA Request/Comment CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: CMC-Site Change for the Blister Pack Foil Lidding

27-Jun-2001 GlaxoSmithKline Correspondence General Correspondence CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: CMC Meeting Minutes for June 14, 2001

27-Jun-2001 GlaxoSmithKline Correspondence General Correspondence CMC Field Copy

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: CMC Field Copy

27-Jun-2001 GlaxoSmithKline Correspondence General Correspondence CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: CMC - 36-Month Stability Update

27-Jun-2001 GlaxoSmithKline Correspondence User Fee Response to Reconciliation Request

# Regulatory Affairs

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30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules  
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Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
All	FDA Invoice 975586 User Fee: Response to Reconciliation Request			
27-Jun-2001	NDA 19-958; CUTIVATE® (fluticasone propionate cream) Cream, 0.05% NDA 21-254; ADVAIR™ HFA (fluticasone propionate/salmeterol) Inhalation Aerosol 44mcg/21mcg, 110mcg/21mcg, 220mcg/21mcg NDA 21-319; Dutasteride Soft-Gelatin Capsules	General Correspondence	CMC Field Copy	
02-Jul-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC Field Copy			
02-Jul-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Other, Financial Disclosure	Response to FDA Request/Comment	Other	
02-Jul-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical	Response to FDA Request/Comment	Nonclinical	
09-Jul-2001	GlaxoSmithKline Correspondence	Amendment to Pending Application	Labeling	

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**Application:** NDA 21319; Dutasteride Soft-Gelatin Capsules

<b>Date Range:</b>	<b>Date</b>	<b>Communication Type</b>	<b>Document Type</b>	<b>Document Subtype</b>	<b>Serial / Supp #</b>
All		NDA 21-319; Dutasteride Soft-Gelatin Capsules Amendment to Pending Application: Tradename; Labeling			

13-Jul-2001      GlaxoSmithKline Correspondence      Response to FDA Request/Comment      Labeling

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Labeling

16-Jul-2001      GlaxoSmithKline Telephone Conversation      General Teleconference      CMC

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Teleconference: CMC

16-Jul-2001      GlaxoSmithKline Correspondence      Minutes of Meeting      FDA Conference

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Minutes of Meeting

20-Jul-2001      GlaxoSmithKline Correspondence      Amendment to Pending Application      Clinical Labeling  
Nonclinical

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Amendment to Pending Application: Labeling, Nonclinical, Human Pharmacokinetics

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
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20-Jul-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Statistical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Statistical

26-Jul-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Nonclinical

30-Jul-2001	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment

30-Jul-2001	Food and Drug Administration Correspondence	Minutes of Meeting	FDA Conference	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Minutes of Meeting

02-Aug-2001	Food and Drug Administration FAX/E-mail	Comment/Information Request	Nonclinical	
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# Regulatory Affairs CARDS

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30-Nov-2001  
Applications: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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	All	NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Nonclinical			
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07-Aug-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Nonclinical

14-Aug-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Statistical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Statistical

20-Aug-2001		Food and Drug Administration Correspondence	Comment/Information Request	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Comment/Information Request: CMC

23-Aug-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Clinical Efficacy	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment

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30-Nov-2001  
Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date	Date Range:	Communication Type	Document Type	Document Subtype	Serial / Supp #
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04-Sep-2001	All	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Nonclinical

06-Sep-2001		GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment	Statistical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Statistical

07-Sep-2001		GlaxoSmithKline Correspondence	General Correspondence	Clinical Statistical	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: Clinical, Statistical

07-Sep-2001		GlaxoSmithKline Correspondence	Response to FDA Request/Comment	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: CMC - August 27, 2001

10-Sep-2001		Food and Drug Administration Correspondence	User Fee Invoice	Product	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules

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30-Nov-2001					
Application:	NDA	21319; Dutasteride Soft-Gelatin Capsules		Chronology	
Date Range:	All				
Date	Communication Type	Document Type		Document Subtype	Serial / Supp #
	"User Fee Invoice				
13-Sep-2001	GlaxoSmithKline Telephone Conversation	Response to FDA Request/Comment		Clinical Statistical	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Clinical, Statistical				
19-Sep-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment		Clinical Statistical	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Clinical, Statistical				
25-Sep-2001	GlaxoSmithKline Telephone Conversation	General Teleconference		CMC	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: CMC				
26-Sep-2001	GlaxoSmithKline Telephone Conversation	General Teleconference		CMC	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules General Teleconference: CMC				



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30-Nov-2001

Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
27-Sep-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC	General Correspondence	CMC	
01-Oct-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC	Response to FDA Request/Comment	CMC	
04-Oct-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules General Correspondence: CMC	General Correspondence	CMC	
04-Oct-2001	Food and Drug Administration Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Clinical	Comment/Information Request	Clinical	
09-Oct-2001	GlaxoSmithKline Correspondence  NDA 21-319; Dutasteride Soft-Gelatin Capsules Amendment to Pending Application: CMC	Amendment to Pending Application	CMC	

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**Application:** NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: Date	Communication Type	Document Type	Document Subtype	Serial / Supp #
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09-Oct-2001	Food and Drug Administration Telephone Conversation	General Teleconference	Meeting Agenda or Details Meeting Request	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Teleconference: Meeting Request

09-Oct-2001	Food and Drug Administration Correspondence	Minutes of Meeting Comment/Information Request	FDA Conference CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Minutes of September 25 CMC Meeting

10-Oct-2001	Food and Drug Administration Correspondence	Minutes of Meeting	FDA Conference	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Minutes of Meeting: FDA Conference

11-Oct-2001	GlaxoSmithKline Correspondence	Amendment to Pending Application	CMC	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Amendment to Pending Application: CMC

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30-Nov-2001

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range:	All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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11-Oct-2001

GlaxoSmithKline Correspondence

General Correspondence

CMC Field Copy

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: CMC Field Copy

11-Oct-2001

GlaxoSmithKline Telephone Conversation

General Teleconference

Clinical  
Nonclinical  
SafetyNDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Teleconference: Clinical, Nonclinical, Safety

15-Oct-2001

GlaxoSmithKline Correspondence

General Correspondence

Labeling  
OtherNDA 21-319; Dutasteride Soft-Gelatin Capsules  
General Correspondence: Other, Trade Name

15-Oct-2001

GlaxoSmithKline Telephone Conversation

Response to FDA Request/Comment

Advisory Committee Meeting

NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment  
Clinical Pharmacology and Biopharmaceutics Review Letter

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Application:

NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
17-Oct-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Minutes of Meeting: FDA Conference	Minutes of Meeting	FDA Conference	
18-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules NDA 20-241: LAMICTAL® (lamotrigine) Tablets General Correspondence: Request for a User Fee Refund Check	General Correspondence	Other	
24-Oct-2001	GlaxoSmithKline Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: CMC	Response to FDA Request/Comment	CMC	
24-Oct-2001	Food and Drug Administration Correspondence NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling	Comment/Information Request	Labeling	
31-Oct-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	BA/BE Clinical	

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Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment

02-Nov-2001	GlaxoSmithKline FAX/E-mail	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Labeling

05-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Labeling

07-Nov-2001	Food and Drug Administration Correspondence	User Fee Invoice Comment/Information Request		
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
NDA 20-241; LAMICTAL® (lamotrigine) Tablet  
Re: GlaxoSmithKline, Request for Refund of Application Fees  
User fee ID #4203 and #4204

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30-Nov-2001

Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

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Date Range: Date	All Communication Type	Document Type	Document Subtype	Serial / Supp #
08-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling			
08-Nov-2001	Food and Drug Administration FAX/E-mail	Comment/Information Request	Labeling	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling			
08-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Labeling, Packaging			
13-Nov-2001	Food and Drug Administration FAX/E-mail	Comment/Information Request	Labeling	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Comment/Information Request: Labeling			
15-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Nonclinical	
	NDA 21-319; Dutasteride Soft-Gelatin Capsules Response to FDA Request/Comment: Nonclinical; Phase 4 Commitment			

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30-Nov-2001 Application: NDA 21319; Dutasteride Soft-Gelatin Capsules

Date Range: All	Communication Type	Document Type	Document Subtype	Serial / Supp #
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16-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Labeling

16-Nov-2001	Food and Drug Administration FAX/E-mail	Comment/Information Request	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Comment/Information Request: Labeling

19-Nov-2001	GlaxoSmithKline Correspondence	Response to FDA Request/Comment	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Response to FDA Request/Comment: Labeling

20-Nov-2001	Food and Drug Administration Correspondence	Approval Letter	Labeling	
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NDA 21-319; Dutasteride Soft-Gelatin Capsules  
Approval Letter

30-Nov-2001	GlaxoSmithKline Correspondence	General Correspondence		
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General Correspondence: Other  
Notification of Corporation Name Change - Reproductive and Urologic

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30-Nov-2001

Application: NDA

21319; Dutasteride Soft-Gelatin Capsules

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